

REMARKS

This Amendment cancels method claims 16, 18, 19 and 34 and amends claims 24, 28 and 30-33. The amendment of claims 30-33 is supported by page 15, lines 13-14, page 16, line 22 and Figs. 8, 10 and 12. See also page 15, line 19 ("rate of solubility"). Claims 24-33 are pending.

Entry of this Amendment is earnestly requested, as it is believed (1) to place the application in condition for allowance, (2) not to raise any new issue or require further search, (3) to be directly responsive to the Official Action, and (4) to place this application in even better form for appeal, should such appeal be necessary. The cancellation of claims 16, 18, 19 and 34 cannot raise a new issue. The amendment of claims 24 and 28 to delete "controllably" is consistent with the prior indefiniteness rejection of claims 24-30 for their recitation of "controllably". Thus, the amendment of claims 24 and 28 does not raise a new issue, but rather addresses a *prior* rejection. The replacement of "solubility" with --solubility rate-- does not raise a new issue, but rather is intended to make the claims even more clear to one of ordinary skill in the art.

The cancellation of claims 16, 18, 19 and 34 moots the 35 U.S.C. § 112, first paragraph, rejection of those claims. Reconsideration and withdrawal of the § 112, first paragraph, rejection of claims 34, 16, 18 and 19 are earnestly requested.

The cancellation of claims 16, 18, 19, and 34 moots the 35 U.S.C. § 103(a) rejection of those claims over PCT Patent Publication WO 97/45367 to Ahola et al. Reconsideration and withdrawal of the obviousness rejection of claims 16, 18, 19 and 34 over Ahola et al. are earnestly requested.

The cancellation of claims 16, 18, 19, and 34 moots the 35 U.S.C. § 103(a) rejection of those claims over U.S. Patent No. 4,919,871 to Lin et al. Reconsideration and withdrawal of the obviousness rejection of claims 16, 18, 19 and 34 over Lin et al. are earnestly requested.

The cancellation of claims 16, 18, 19, and 34 moots the 35 U.S.C. § 103(a) rejection of those claims over German patent DE 196 09 551 ("German '551"). Reconsideration and withdrawal of the obviousness rejection of claims 16, 18, 19 and 34 over German '551 are earnestly requested.

The 35 U.S.C. § 103(a) rejection of claims 24-33 over Ahola et al. is traversed. A feature of claims 24-33 is a biodegradable

silica fiber having a solubility rate in simulated body fluid of from 0.2 to 20 wt-%/h. The slowest (0.2 wt-%/hour minimum) solubility rate means that the fiber will completely dissolve in about 21 days.

The Patent Office concedes Ahola et al. fails to disclose the 0.2 to 20 wt-%/hour solubility rate range feature of the claimed biodegradable fiber (Official Action, page 10, line 12). Instead, as previously noted, most of the fibers of Ahola et al.'s Example 2 did not dissolve in vitro at all. The only fiber with appreciable dissolution had a solubility rate of 10 wt-%/4 weeks, or 0.0148 wt-%/hour, which is approximately 20 times slower to dissolve than the claimed biodegradable fiber.

Example 2 of Ahola et al. completely refutes the Patent Office argument that the biodegradability of a silica fiber is solely based on its chemical composition. In fact, the fiber's biodegradability (solubility rate) is based at least partly on the processing parameters used to manufacture the fiber. See paragraph Nos. 9 and 10 of the attached Declaration by Mika Jokinen.

Ahola et al. fails to raise a prima facie case of obviousness against the claimed fiber for at least two reasons. First, prior to the present invention, it was not known that the solubility rate

would increase if the fiber was spun from a sol of higher viscosity.

Second, at the time of the present invention, it was known the viscosity of a sol increases over time. It was also known that production problems related to gelation of the sol can be expected to occur when spinning silica fibers from a late stage, high viscosity sol. Accordingly, one of ordinary skill in the art had no reason or motivation to spin fibers from sols with a very high viscosity.

The fast solubility rate of the claimed fiber is surprising and unexpected because the prior art simply had not achieved such a fast solubility rate. The non-dissolving and slowly-dissolving fibers of Ahola et al. support this position.

Reconsideration and withdrawal of the obviousness rejection of claims 24-33 over Ahola et al. are earnestly requested.

The 35 U.S.C. § 103(a) rejection of claims 24-33 over German patent DE 196 09 551 ("German '551") is respectfully traversed. A feature of claims 24-33 is a biodegradable silica fiber having a solubility rate in simulated body fluid of from 0.2 to 20 wt-%/h.

German '551 fails to raise a prima facie case of obviousness against the claimed fiber (and delivery device, pharmaceutical

composition and method of treatment based thereon) because this reference fails to disclose or suggest the solubility rate range required by the claimed fiber (which will result in complete fiber dissolution in about 21 days for the lower (slower) solubility rate range limit. In contrast, German '551 discloses a fiber whose *fastest* dissolution time is 50 days.

The Official Action argues there is "a suggestion to adjust degradation rate" in German '551. Yet the Patent Office has not provided any evidence that silica fibers having a solubility rate of from 0.2 to 20 wt-%/h were known or that those of ordinary skill in the art could produce such a silica fiber if they wished. In fact, silica fibers with such a fast solubility rate simply had not been achieved by the prior art, as demonstrated by both German '551 (dissolution times of 50 days or more) and Ahola et al. (dissolution time of 40 weeks).

One of ordinary skill in the art simply would not have believed silica fibers with such a fast solubility rate (0.2 to 20 wt-%/h) could be prepared, much less known how to prepare such fibers. It cannot be obvious to try when one of ordinary skill in the art does not know how to produce a silica fiber having the

claimed solubility rate. See paragraph Nos. 14-16 of the attached Declaration by Mika Jokinen.

Reconsideration and withdrawal of the obviousness rejection of claims 24-33 over German '551 are earnestly requested.

It is believed this application is in condition for allowance. Reconsideration and withdrawal of all rejections of claims 16, 18, 19 and 24-34, and issuance of a Notice of Allowance directed to claims 24-33, are earnestly requested. The Examiner is urged to telephone the undersigned should she believe any further action is required for allowance.

A Petition and fee for an Extension of Time are attached. It is not believed any additional fee is required for entry and consideration of this Amendment. Nevertheless, the Commissioner is

U.S. Appln. S.N. 09/913,643
AMENDMENT AFTER FINAL REJECTION

PATENT

authorized to charge our Deposit Account No. 50-1258 in the amount
of any such required fee.

Respectfully submitted,

/James C. Lydon/

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Enclosures:

Petition for Extension of Time
Declaration Under 37 C.F.R. § 1.132